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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,854	10/11/2006	Navin N. Thakkar		5788

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INDIA

EXAMINER

HARVEY, JULIANNA NANCY

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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03/28/2012

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,854	THAKKAR, NAVIN N.	
	Examiner	Art Unit	
	JULIANNA N. HARVEY	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 13-18,20-23 and 28-37 is/are pending in the application.
- 5a) Of the above claim(s) 23,28 and 29 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 13-18,20-22 and 30-37 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 35 is rejected under 35 U.S.C. 101 because it is drawn to non-statutory subject matter. In claim 35, lines 2-3, Applicant positively recites part of a human, i.e. "protruding cut end is out at a distance substantially equal to 1cm from an entry in said bone". Thus claim 35 includes a human within its scope and is non-statutory. A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17, 18, 20-22, 36, and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 17 recites that the

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assembly includes a plurality of flexible nails, an intramedullary rod, and an end cap. As such, claim 17 is drawn to the embodiment shown in Figs. 11A-17. However, claim 17 also recites that each of the flexible nails has two free ends. As shown in Figs. 15-17, each flexible nail only has one free end. The other end is captured by the intramedullary rod and end cap and is therefore not a free end. Accordingly, claims 17, 18, 20-22, 36, and 37 contain new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 33 and 34 both recite the limitation "plurality of flexible nails" in line 2. There is insufficient antecedent basis for this limitation in the claim as claim 13 recites a single flexible nail.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-16 and 30-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Walker (US 4,457,301 A). **Claim 13:** Walker discloses an orthopedic implant flexible intramedullary nail comprising: a single flexible nail (11) of universal

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length having a first free end (upper end 12), a second free end (lower end 12) and a shaft defining a long axis of the nail wherein the shaft and the ends have a plurality of curvatures at a plurality of planes along the long axis (col. 2, ll. 48-64) thereby allowing the nail to fix, reposition, and maintain relation of fragments of a bone at multiple contact points of fixation inside a medullary canal of the bone (Fig. 1). **Claim 15:** Walker discloses that the nail (11) is made from material comprising one of 316 L (low carbon) or 316 LVM (low carbon vacuum melted) stainless steel or other biocompatible material (Fig. 1; col. 2, ll. 48-64). **Claim 16:** Walker discloses that the first and second ends (12) are identical (Fig. 1). **Claim 30:** Walker discloses that the shaft has a first cross section diameter (near line drawn from ref. char. 11), the first and second ends (12) have a second cross section diameter (near line drawn from ref. char. 12), wherein the second diameter is smaller than the first diameter (Fig. 1). **Claim 31:** Walker discloses that the nail (11) has a uniform surface along the whole length (Fig. 1). **Claim 32:** Walker discloses that the first free end (upper end 12) and the second free end (lower end 12) have a conical path finder tip (Fig. 1). **Claim 33:** Walker discloses additional nails (11 – see Fig. 4) such that there is a plurality of nails (11) where each one of the nails is mutually free from each one another of the nails along the whole length of the flexible nail (Fig. 4). **Claim 34:** Walker discloses additional nails (11 – see Fig. 4) such that there is a plurality of nails (11) characterized where each one of the nails is freely repositionable relative to each one another of the nails (Fig. 4). Walker does not explicitly state that the nail has 15%-25% of elongation on tensile stress (**claim 13**) and that the nail has ultimate tensile strength of about 600-800 MPa (**claim 14**). However,

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the 15%-25% corresponds to ductility and ductility and tensile strength are properties of a given material. Because the Walker nail is made from the same material as Applicant's invention (see col. 2, ll. 48-64), the examiner is taking the position that the ductility of the Walker nail is 15%-25% of the elongation of the nail and the ultimate tensile strength is about 600-800 MPa. Therefore, Walker anticipates **claims 13 and 14**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walker (US 4,457,301 A) in view of Durham et al. (US 6,106,528 A). Walker discloses the claimed invention except that an end of the nail is roughened. Durham et al. teach a nail (223) wherein an end (229) of the nail is roughened to provide means for the

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surgeon to grip the nail (Fig. 62; col. 26, ll. 31-33). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the nail of Walker such that an end is roughened, as suggested by Durham et al., as doing so would provide means for the surgeon to grip the nail.

Response to Arguments

Applicant's arguments with respect to claims 13 and 17 have been considered but are moot because the arguments do not apply to any of the references being used in the current rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIANNA N. HARVEY whose telephone number is (571)270-3815. The examiner can normally be reached on Monday through Friday, from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Eduardo C. Robert, at 571-272-4719.*** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JNH/

Julianna Harvey
Examiner, Art Unit 3733

/EDUARDO C. ROBERT/

Supervisory Patent Examiner, Art Unit 3733